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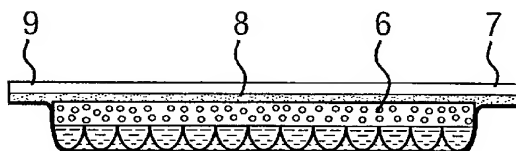
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(54) Title: APERTURED HYDROGEL WOUND DRESSING



(57) Abstract: An absorbent article comprising: a continuous cover sheet having a plurality of projections formed therein; and a sterile hydrogel layer in contact with the cover sheet such that said projections extend through the hydrogel layer. The cover sheet can be removed to provide an apertured hydrogel sheet suitable for contacting exuding wounds also methods of making such absorbent articles are provided..



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## APERTURED HYDROGEL WOUND DRESSING

The present invention relates to apertured hydrogel sheets for use as or in wound dressings and other absorbent articles.

5

It is known to use apertured hydrogel sheets as the wound contacting layer in multilayered wound dressing. The hydrogel absorbs water to form a moist, non-adherent wound facing layer in use. The apertures allow excess wound exudate to pass through the hydrogel layer into a more conventional secondary absorbent layer, such as a nonwoven fabric layer.

10

US-A-5352508 describes an apertured substrate web coated with a hydrogel material for use as a wound facing layer in wound dressings.

15 EP-A-0532275 describes a non-reinforced hydrogel dressing in the form of an apertured web. The dressing may be formed by casting an aqueous solution of a water-soluble polysaccharide or cellulose derivative and a humectant onto a mold comprising a plurality of interconnected grooves surrounding a plurality of upstanding bosses, and drying the solution in the mold to form the dressing having  
20 a pattern of apertures corresponding to the upstanding bosses of the mold. The web dressing is then separated from the mold before packaging, and the mold is reused.

WO00/65143 describes a method of coating a perforated substrate with a gel  
25 without substantial occlusion of the perforations, which process comprises (i) forming a layer of a liquid pregel mixture, comprising one or more monomers, on a web coated with a coating having a surface energy less than the surface energy of the liquid pregel mixture; (ii) contacting the perforated substrate with the liquid pregel mixture; and (iii) curing the liquid pregel mixture.

30

GB-A-2093702 describes open elastomeric webs for use as the wound facing layer in dressings for burns and other exuding wounds. The webs may be made by casting a precursor solution onto a plastic sheet that has been embossed with

the pattern of the web, followed by curing and drying the precursor solution on the sheet and stripping the resulting web from the sheet. In certain embodiments, an absorbent foam layer and backing sheet may be laminated to the elastomeric net while the net is still on the embossed sheet carrier.

5

US-A-5076265 describes a hydrogel sheet for use as a wound dressing having capillaries permitting wound exudate to pass through the sheet. The capillaries may be drilled out of the sheet using hollow needles or syringes, or they may be formed by casting the hydrogel sheets in molds having a series of upward  
10 projections such that on removal of the sheets from the mold, appropriate capillaries are formed.

A need remains for an improved way of making apertured hydrogel sheets for use in wound dressings and other articles for absorbing bodily fluids.

15

The present invention provides an absorbent article comprising: a continuous cover sheet having a plurality of projections formed therein; and a sterile hydrogel layer in contact with the cover sheet such that said projections extend through the hydrogel layer.

20

The absorbent article may preferably be a wound dressing, especially for use on exuding wounds, in which case the hydrogel layer would normally be the wound contacting layer in use. The absorbent article may be suitable for absorbing other bodily fluids, including incontinence devices, catamenial devices, diapers and  
25 colostomy devices.

The cover sheet is normally peeled from the hydrogel layer immediately before use. This construction provides support and protection to the hydrogel layer during manufacture and storage, and also provides a high degree of control over  
30 the final form of the hydrogel layer at low cost, since the cover sheet also forms part of the packaging of the hydrogel layer.

Preferably, the area of the hydrogel layer is from about  $1\text{cm}^2$  to about  $400\text{ cm}^2$ , more preferably from about  $4\text{cm}^2$  to about  $100\text{cm}^2$ . Preferably, the cover sheet is larger than the hydrogel layer such that a marginal region of width 1mm to 50 mm, preferably 5mm to 20mm extends around the hydrogel layer.

5

Preferably, the article further comprises a protective sheet extending over the hydrogel layer and bonded to the cover sheet in a marginal region around the hydrogel layer so as to enclose the sterile hydrogel layer. The resulting enclosure keeps the hydrogel sterile until the cover layer is peeled off immediately before

10 use.

The absorbent article is packaged. That is to say, at least the cover sheet must be peeled from the hydrogel layer before the article can be used. Preferably, the enclosure provided by the cover sheet and the protective sheet is microorganism-

15 impermeable, and the hydrogel is sterile. This arrangement removes the need for any further microorganism-impermeable packaging, although such secondary packaging may be present in certain embodiments, in which case the whole article may be sterilized.

20 Preferably, the protective sheet is itself the backing sheet of the absorbent article. For example, it may comprise a semipermeable film, such as a microporous polyurethane film, of the kind used in island-type wound dressings. In such cases, the backing sheet is preferably coated with a pressure sensitive medical grade adhesive in at least its marginal region, and the cover sheet is provided with a

25 release surface for the adhesive in at least its marginal region, so that the protective/backing sheet with the adhesive coating can be peeled from the cover sheet prior to application directly to the skin of a user. The resulting article is a self-contained sterile packaged hydrogel island wound dressing.

30 Preferably, the backing sheet is substantially liquid-impermeable. The backing sheet is preferably semipermeable. That is to say, the backing sheet is preferably permeable to water vapour, but not permeable to liquid water or wound exudate. Preferably, the backing sheet is also microorganism-impermeable. Suitable

continuous conformable backing sheets will preferably have a moisture vapor transmission rate (MVTR) of the backing sheet alone of 300 to 5000 g/m<sup>2</sup>/24hrs, preferably 500 to 2000 g/m<sup>2</sup>/24hrs at 37.5 °C at 100% to 10% relative humidity difference. The backing sheet thickness is preferably in the range of 10 to 1000  
5 micrometers, more preferably 100 to 500 micrometers.

The MVTR of the dressing according to the present invention as a whole is lower than that of the backing sheet alone, because the apertured sheet partially obstructs moisture transfer through the dressing. Preferably, the MVTR of the  
10 dressing (measured across the island portion of the dressing) is from 20% to 80% of the MVTR of the backing sheet alone, more preferably from 20% to 60% thereof, and most preferably about 40% thereof. It has been found that such moisture vapor transmission rates allow the wound under the dressing to heal under moist conditions without causing the skin surrounding the wound to  
15 macerate.

Suitable polymers for forming the backing sheet include polyurethanes and polyalkoxyalkyl acrylates and methacrylates such as those disclosed in GB-A-1280631. Preferably, the backing sheet comprises a continuous layer of a high  
20 density blocked polyurethane foam that is predominantly closed-cell. A suitable backing sheet material is the polyurethane film available under the Registered Trade Mark ESTANE 5714F.

The adhesive (where present) layer should be moisture vapor transmitting and/or  
25 patterned to allow passage of water vapor therethrough. The adhesive layer is preferably a continuous moisture vapor transmitting, pressure-sensitive adhesive layer of the type conventionally used for island-type wound dressings, for example, a pressure sensitive adhesive based on acrylate ester copolymers, polyvinyl ethyl ether and polyurethane as described for example in GB-A-1280631. The basis  
30 weight of the adhesive layer is preferably 20 to 250 g/m<sup>2</sup>, and more preferably 50 to 150 g/m<sup>2</sup>. Polyurethane-based pressure sensitive adhesives are preferred.

Preferably, the adhesive layer extends outwardly from the absorbent layer and the envelope to form an adhesive-coated margin on the backing sheet around the adhesive layer as in a conventional island dressing.

- 5 Further layers of a multilayer absorbent article may be built up between the hydrogel layer and the protective sheet. For example, these layers may comprise an apertured plastic film to provide support for the hydrogel layer in use, in which case the apertures in the film are preferably aligned in register with the apertures in the hydrogel layer.

10

The apertured film may be formed from any suitable thermoplastic film-forming polymer. Preferably, the polymer is conformable but not substantially elastomeric. Suitable polymers include, but are not limited to, polyethylene, polypropylene, polyester, polyamides such as nylons, fluoropolymers such as polyvinylidene fluoride (PVDF) or polytetrafluoroethylene (PTFE), and mixtures thereof. The top sheet is preferably a polyolefin film. Preferably, the film has a thickness by weight (ASTM E252-84) of from 10 to 200 micrometers, more preferably from 25 to 100 micrometers.

- 20 The apertured support film in these embodiments is liquid permeable, but in certain preferred embodiments the film structure acts to block or restrict the flow of liquid from the back surface of the film to the wound-facing hydrogel side. That is to say, the apertured support film allows fluid to pass through the top sheet from the hydrogel, but blocks or restricts flow of the fluid back through the top sheet to the hydrogel side (also known as wet-back). Preferably, the plastic film has greater liquid permeability to the flow of liquid away from the wound facing surface than to the flow of liquid towards the wound facing surface.

- For example, such a film may be formed from a substantially liquid-impermeable sheet material provided with tapered capillaries, each capillary having a base substantially in the plane of the wound facing surface of the film and an apical opening remote from the wound facing surface of the film and preferably in contact with an absorbent layer. The conical capillaries provide rapid one-way wicking of
- 30

fluid from the front of the top sheet, with minimal wet-back. Top sheets of this type are described in GB-A-1526778.

Alternatively or additionally, the multilayer absorbent article according to the present invention may include one or more liquid-absorbent layers between the hydrogel layer and the protective sheet. The optional absorbent layer may be any of the layers conventionally used for absorbing wound fluids, serum or blood in the wound healing art, including gauzes, nonwoven fabrics, superabsorbents, hydrogels and mixtures thereof. Preferably, the absorbent layer comprises a layer of absorbent foam, such as an open celled hydrophilic polyurethane foam prepared in accordance with EP-A-0541391, the entire content of which is expressly incorporated herein by reference. In other embodiments, the absorbent layer may be a nonwoven fibrous web, for example a carded web of viscose staple fibers. The basis weight of the absorbent layer may be in the range of 50-500g/m<sup>2</sup>, such as 100-400g/m<sup>2</sup>. The uncompressed thickness of the absorbent layer may be in the range of from 0.5mm to 10mm, such as 1mm to 4mm. The free (uncompressed) liquid absorbency measured for physiological saline may be in the range of 5 to 30 g/g at 25°. Preferably, the absorbent layer or layers are substantially coextensive with the hydrogel layer.

20

The cover sheet is normally formed from flexible thermoplastic material. Suitable materials include polyesters and polyolefins. Preferably, the hydrogel facing surface of the cover sheet is a release surface. That is to say, a surface that is only weakly adherent to the hydrogel to assist peeling of the hydrogel layer from the cover sheet. For example, the cover sheet may be formed from a non-adherent plastic such as a fluoropolymer, or it may be provided with a release coating such as a silicone or fluoropolymer release coating.

Preferably, the cover sheet is provided with a recess in the central region, the projections in the cover sheet extend into the recess, and the hydrogel layer is received in the recess. The recess is typically a shallow recess dimensioned to receive the hydrogel layer and any additional layers such as perforated layers or absorbent layers that are coextensive with the hydrogel layer. Typically the depth

30

of the recess is from 1 to 10 mm, preferably from 2 to 8 mm. The recess may be provided by thermoforming.

The cover sheet acts as a mold for the hydrogel, and the projections in the cover sheet define the shape of apertures in the hydrogel layer. It is a particular advantage of the present invention that this enables the porosity of the hydrogel layer to be controlled accurately. The projections may be square or cylindrical, but preferably the projections in the cover sheet are tapered, whereby apertures in the hydrogel layer are correspondingly tapered.

10

Preferably, the projections are substantially in the form of tapered geometric bodies such as truncated cones, pyramids or the like. Preferably, the projections of such tapered projections have a base dimension of from 0.5 mm to 5 mm, and an apical dimension (at the top surface of the hydrogel layer) of from 0.05 to 2 mm. More preferably, the projections have a base dimension as herein defined of from 1 mm to 3 mm, and an apical dimension of from 0.1 to 1 mm.

20

Preferably, the projections have an average angle of taper (measured from the perpendicular to the plane of the cover sheet) of from 10 to 60 degrees.

Preferably, the height of the projections is from 0.1 to 5 mm, more preferably from 1 to 3 mm. Preferably, the density of the projections is from 1 to 400 per  $\text{cm}^2$ , more preferably from 10 to 100 per  $\text{cm}^2$ . Preferably, the mean cross sectional area of the projections at their mid-point (half height) is from about 1 to about 50%, preferably about 5 to about 50% of the total area of the central region of the top sheet, more preferably from about 10 to about 25% of the said total area. Preferably, the projections are arranged in a regular array.

Projections of this type may be manufactured, for example, by embossing or thermoforming or injection molding of the cover sheet.

Preferably, the cover sheet and/or the protective sheet is transparent to visible and/or ultraviolet light. This provides an attractive visual appearance, and also



means that the certain hydrogels can be cured using visible and/or UV radiation through the cover sheet and/or through the protective sheet.

Preferably, the hydrogel layer has a dry basis weight of from 10 to 200g/m<sup>2</sup>, more preferably from 10 to 100g/m<sup>2</sup>, and most preferably from 10 to 50g/m<sup>2</sup>. In certain embodiments the hydrogel layer has a thickness as determined by ASTM D374-79 of from about 0.2 to about 4 mm. The hydrogel layer is sterile. The cover sheet and the protective sheet function as a primary packaging for the hydrogel layer, maintaining it sterile until use. The overall process to make the dressing is simplified, and there is no need for a separate mold to cast the apertured hydrogel sheet.

The term "hydrogel layer" refers generally to layers that interact with the wound surface under physiological conditions to maintain an elevated moisture level at the wound surface. Preferably, the hydrogel layer forms a gel with water under physiological conditions of temperature and pH. In certain embodiments, the hydrogel layer absorbs at least 50% w/w of water on immersion at 25°C for 60 minutes, based on the weight of the hydrogel before immersion. Such hydrogel layers can be formed by the inclusion of medically acceptable macromolecular materials that preferably have the ability to swell and absorb fluid while maintaining a strong integral structure. Preferably, the hydrogel composition forms a gel that is substantially insoluble in water under physiological conditions, whereby the hydrogel is not washed away by the wound fluid. The hydrogel may be a biopolymer, and/or it may be bioabsorbable. That is to say, it may undergo gradual resorption *in vivo*.

Exemplary insoluble gels include certain cross-linked polyacrylate gels, calcium alginate gels, cross-linked hyaluronate gels, wherein the hydrogel layer comprises a hydrogel material selected from gels formed from vinyl alcohols, vinyl esters, vinyl ethers and carboxy vinyl monomers, meth(acrylic) acid, acrylamide, N-vinyl pyrrolidone, acylamidopropane sulphonic acid, PLURONIC (Registered Trade Mark) (block polyethylene glycol, block polypropylene glycol) polystyrene-, maleic

acid, NN-dimethylacrylamide diacetone acrylamide, acryloyl morpholine, and mixtures thereof.

Preferably, the hydrogel layer comprises a hydrogel material selected from  
5 polyurethane gels, biopolymer gels, carboxymethyl cellulose gels, hydroxyethyl cellulose gels, hydroxy propyl methyl cellulose, modified acrylamide and mixtures thereof. Suitable biopolymer gels include alginates, pectins, galactomannans, chitosan, gelatin, hyaluronates and mixtures thereof. Some of these biopolymer materials also promote wound healing.

10

Preferably, the macromolecular materials making up the gels are cross-linked, and the cross-linking may be either covalent or ionic.

The hydrogel material may further comprise from 5 to 50% by weight on a dry  
15 weight basis of one or more humectants such as glycerol

For example, the hydrogel layer comprise a hydrogel material of the kind described in WO00/07638, the entire content of which is incorporated herein by reference.

20

Alternatively or additionally to the gel-forming macromolecules, the hydrogel layer may comprise one or more emollients. Emollients are used to smooth the surface of skin and to increase the degree of hydration. They act either by occluding water loss from the outer layer of the skin, or by improving water binding to the skin.  
25 Emollients are particularly useful in the treatment of atopic eczemas and ichthyoses. Preferred emollients include White Soft Paraffin, Yellow Soft Paraffin, Liquid paraffin, Urea Creams, Lanolin, Sodium Pyrrolidone Carboxylate (PCA Na), Evening primrose extract (gamma linolenic acid), Soya Oil, Tea Tree Oil, Coconut Oil, Almond Oil, Camomile Extract, Cod Liver Oil, Peanut Oil, Emu Oil, Aloe Vera,  
30 Sunflower oil, Avocado Oil, Jojoba Oil, Cocoamide, and mixtures thereof.

The hydrogel layer may additionally comprise one or more active therapeutic or antimicrobial agents. Suitable therapeutic agents include growth factors,

analgesics, local anaesthetics and steroids. Suitable antimicrobial agents include antiseptics such as silver compounds and chlorhexidine, and antibiotics. The therapeutic or antimicrobial agents are usually added in an amount of from 0.01% to 5% by weight, based on the dry weight of the hydrogel layer.

5

The present invention further provides a packaged wound dressing comprising an absorbent article according to the present invention. A wound dressing is provided by peeling the hydrogel layer from the protective cover sheet.

- 10 The present invention further provides a method of making an absorbent article comprising the steps of: providing a continuous cover sheet having a plurality of projections formed in a central region thereof; forming a hydrogel layer in contact with the central region of the cover sheet, with said projections extending through the hydrogel layer to define a plurality of apertures in the hydrogel layer; followed  
15 by sterilizing the hydrogel and the cover sheet.

Preferably, the method according to the present invention is adapted to provide an absorbent article according to the present invention.

- 20 The step of providing a continuous cover sheet having projections in a central region thereof may be done by thermoforming, embossing or injection molding, as described above. The term "continuous" signifies that the cover sheet is substantially impermeable to liquids and microorganisms, but it may have some gas permeability.

25

- The step of forming a hydrogel layer in contact with the cover sheet typically comprises coating the central region of the cover sheet with a fluid pregel composition, followed by treating the pregel composition to form the hydrogel in situ. The pregel composition forms a hydrogel upon cooling, polymerisation or  
30 cross-linking. Examples include aqueous sodium alginate, which can be gelled by calcium salts. Another example is guar gum, which can be gelled by borate salts. In other embodiments, the pregels are curable compositions that comprise one or more monomers and typically one or more crosslinking agents and/or

polymerisation initiators. Preferred monomers are acrylate esters, such as 2-hydroxyethyl methacrylate, acrylamides such as N,N-dimethylacrylamide. Also preferred are mixtures of salts or C1-C5 esters of 2-acrylamide-2-methylpropanesulfonic acid and salts or C1-C5 alkyl esters of acrylic acid (3-sulfopropyl) ester. Suitable cross linking agents are polyethylene glycol diacrylates. Suitable initiators are conventional peroxide initiators.

Suitable pregel materials are the UV-curable polyacrylate pregels described for example in WO00/65143, the entire content of which is incorporated herein by reference.

The pregel can be coated onto the cover sheet for example by spraying or slot coating or extrusion or by means of a doctor blade.

Optional additional layers such as a perforated plastic film and/or absorbent layers can be laminated onto the hydrogel layer before, during or after curing/setting of the hydrogel layer is complete. Likewise, the protective sheet can be applied over the cover sheet and hydrogel before, during or after setting of the hydrogel is complete. The absorbent article may then be sterilized, for example by gamma irradiation, or optionally packaged in secondary packaging and sterilized.

An embodiment of the present invention will now be described further, by way of example, with reference to the accompanying drawings, in which:

Figure 1 shows a cross section through a cover sheet for use in an embodiment of the present invention (vertical dimensions have been enlarged for clarity);

Figure 2 shows a cross section through the cover sheet of Figure 1 with a layer of hydrogel formed on the cover sheet;

Figure 3 shows a cross sectional view through the whole absorbent article according to this embodiment of the invention; and

Figure 4 shows a cross sectional view through the absorbent article of Figure 3 after removal of the cover sheet and prior to attachment of the article to the body.

Example 1

A hydrogel wound dressing according to the invention is prepared as follows.

5

Referring to Figure 1, a cover sheet 1 is provided consisting of a polyester film of thickness about 0.1mm that has been thermoformed to provide a central recess 2 of depth about 2mm and a plurality of projections 3 of height about 1mm extending into the recess 2. The upper surface 4 of the cover sheet is coated with a silicone  
10 release coating.

The bottom of the recess 2 is then coated with a layer of polyurethane hydropolymer pregel 5 as shown in Fig.2 that is applied by spraying. The pregel consists of a mixture of 25 parts by weight of an isocyanate-capped  
15 ethyleneoxy/propyleneoxy prepolymer (HYPOL PreMA G60 (Registered Trade Mark) from Dow Corning Ltd.) and 100 parts by weight of water.

Before curing of the polyurethane gel layer is complete, a layer of polyurethane foam is formed separately on a release sheet. The composition of the foam layer  
20 is:

HYPOL	50%
Water	32%
Acrylic copolymer <sup>b</sup>	12%
Methanol	6%

25 <sup>b</sup> PRIMAL B-15J or RHOPLEX N-560 ( Registered Trade Marks).

The hydrogel and foam sheets are allowed to cure partially for about 90 seconds at ambient temperature, and then the foam layer is pressed gently onto the hydrogel in the cover sheet and the combination is placed in an oven for about 15  
30 minutes to complete the curing and drying. The resulting laminate has the hydrogel layer 5 chemically bonded to the polyurethane foam absorbent layer 6.

The cover sheet has about 10 conical projections per  $\text{cm}^2$ , each perforation having a mid-height diameter in the range of about 0.8- 1.2 mm, resulting in an apertured area of about 5-10% of the total area of the hydrogel sheet.

- 5 Next, the cover sheet and polyurethane layers are covered by a protective backing layer 7 of microporous liquid-impermeable polyurethane foam, such as ESTANE 5714F (Registered Trade Mark). The backing layer is permeable to water vapor, but impermeable to wound exudate and microorganisms. The backing layer 7 is coated with a substantially continuous layer 8 of pressure-sensitive polyurethane  
10 adhesive. The adhesive is adhered to the cover sheet around the margin 9 of the cover sheet to form a substantially microorganism-impermeable enclosure for the polyurethane foam and hydrogel layers.

- The dressing can be sterilized directly for use, for example by gamma irradiation,  
15 or it can be packaged in a secondary package and then sterilized by gamma irradiation.

- In use, the dressing is removed from any secondary package, and the cover sheet is peeled from the backing sheet 7 and the hydrogel layer 5. The resulting  
20 dressing, shown in Fig. 4, has an apertured hydrogel wound facing sheet ready for application to a wound. The apertured hydrogel sheet is applied to the wound with the hydrogel in contact with the wound to provide a sterile and absorbent dressing. The hydrogel sheet interacts with wound exudate to provide a moist but not wet wound environment for a wide range of wounds over an extended period. The  
25 adhesive-coated margin of the backing sheet is adhered to intact skin around the wound in the usual way for island-type dressings.

- The above embodiments have been described by way of example only. Many other embodiments falling within the scope of the accompanying claims will be  
30 apparent to the skilled reader.

## CLAIMS

1. An absorbent article comprising:  
a continuous cover sheet having a plurality of projections formed therein;  
5 and  
a sterile hydrogel layer in contact with the cover sheet such that said projections extend through the hydrogel layer.
2. An absorbent article according to claim 1, further comprising a protective  
10 sheet extending over the hydrogel layer and bonded to the cover sheet in a marginal region around the hydrogel layer so as to enclose the sterile hydrogel layer.
3. An absorbent article according to claim 2, wherein the protective sheet is  
15 coated with an adhesive in at least said marginal region, and the cover sheet is provided with a release surface for said adhesive at least in said marginal region.
4. An absorbent article according to any preceding claim, wherein the article is sterile and packaged in a secondary microorganism-impermeable container.  
20
5. An absorbent article according to any preceding claim, wherein the cover sheet comprises a recess in a central region thereof, the said projections extend into the recess, and the hydrogel layer is received in the recess.
- 25 6. An absorbent article according to any preceding claim, wherein the projections on the cover sheet are tapered.
7. An absorbent article according to any preceding claim, wherein the cover sheet is transparent to visible and/or ultraviolet light.  
30
8. An absorbent article according to any preceding claim, wherein the hydrogel layer absorbs at least 50% w/w of water on immersion at 25°C for 60 minutes, based on the weight of the hydrogel before immersion.

9. An absorbent article according to any preceding claim, wherein the hydrogel layer has a dry basis weight of from 10 to 1000 g/m<sup>2</sup>.
- 5 10. An absorbent article according to any preceding claim, wherein the hydrogel layer has a thickness as determined by ASTM D374-79 of from about 0.2 to about 4 mm.
11. An absorbent article according to any preceding claim, wherein the  
10 hydrogel layer comprises a hydrogel selected from polyurethane gels, gelatin gels, pectin gels, alginate gels, glycosaminoglycan gels, hyaluronic acid gels, guar gels, xanthan gels, gels formed from starch derivatives, carboxymethyl cellulose gels, hydroxyethyl cellulose gels, hydroxypropyl methyl cellulose, polyethylene oxides and mixtures thereof.
- 15 12. An absorbent article according to any preceding claim, wherein the hydrogel layer comprises a hydrogel selected from gels formed by polymerising or copolymerising vinyl alcohols, vinyl esters, vinyl ethers and carboxy vinyl monomers, meth(acrylic) acid, vinyl amide monomers, anionic vinyl monomers,  
20 hydroxy vinyl monomers, cationic vinyl monomers containing amines or quaternary groups, ionic acrylamide derivatives, N-alkyl acrylamides, acrylate esters, ionic acrylate ester derivatives, N-vinyl pyrrolidone, acylamidopropane sulphonic acid, maleic acid, NN- dimethylacrylamide, diacetone acrylamide or acryloyl morpholine.
- 25 13. An absorbent article according to any preceding claim, wherein the hydrogel layer comprises a chemically or physically cross-linked hydrogel-forming polymer.
14. A packaged wound dressing comprising an absorbent article according to  
30 any preceding claim.
15. A method of making an absorbent article comprising the steps of:



providing a continuous cover sheet having a plurality of projections formed in a central region thereof;

forming a hydrogel layer in contact with the central region of the cover sheet, with said projections extending through the hydrogel layer to define a  
5 plurality of apertures in the hydrogel layer; followed by  
sterilizing the hydrogel and the cover sheet.

16. A method of making An absorbent article according to claim 15, wherein the absorbent article is as defined in any of claims 1 to 14.

FIG. 1

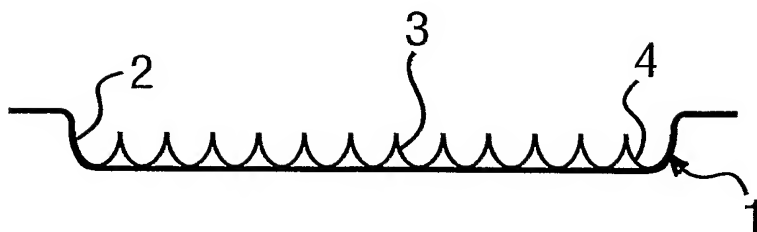


FIG. 2



FIG. 3

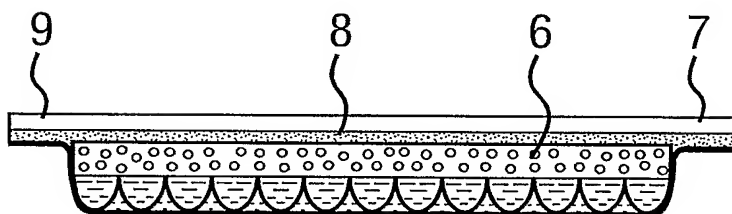
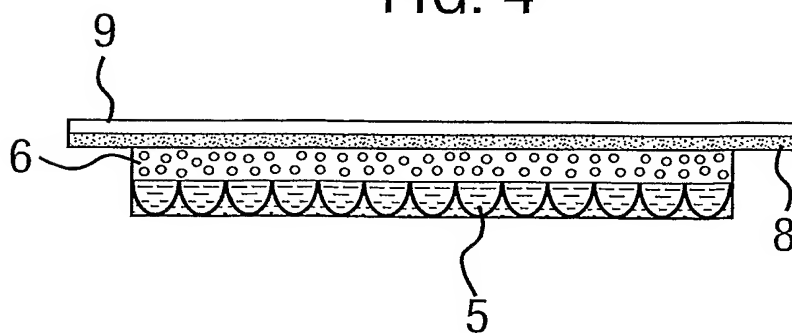


FIG. 4



## INTERNATIONAL SEARCH REPORT

PCT/GB 03/01588

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A61F13/02

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F C09J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

PAJ, EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	PATENT ABSTRACTS OF JAPAN vol. 017, no. 622 (C-1130), 17 November 1993 (1993-11-17) & JP 05 192363 A (TERUMO CORP), 3 August 1993 (1993-08-03) abstract; figures ---	1-6,8-14
Y	DE 37 23 596 A (SQUIBB & SONS INC) 26 January 1989 (1989-01-26) abstract; claims 1,7,8 column 2, line 18 - line 21 column 2, line 32 - line 39 ---	1,4,6,14
Y	EP 0 571 700 A (MLI ACQUISITION CORP II) 1 December 1993 (1993-12-01) page 3, line 15 - line 26; claim 1; figures 1-4 --- -/--	2,3,5, 11-13

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

25 August 2003

Date of mailing of the international search report

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## INTERNATIONAL SEARCH REPORT

PCT/GB 03/01588

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 98 17215 A (SHERWOOD MEDICAL CO) 30 April 1998 (1998-04-30) examples -----	8
Y	EP 0 344 913 A (MINNESOTA MINING & MFG) 6 December 1989 (1989-12-06) abstract; figures -----	9
Y	WO 01 60296 A (3M INNOVATIVE PROPERTIES CO) 23 August 2001 (2001-08-23) page 10, line 23 - line 24 -----	10

# INTERNATIONAL SEARCH REPORT

Information on patent family members

PCT/GB 03/01588

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
JP 05192363	A	03-08-1993	NONE	
DE 3723596	A	26-01-1989	DE 8709810 U1 DE 3723596 A1	08-10-1987 26-01-1989
EP 0571700	A	01-12-1993	AU 2600692 A BR 9203999 A CA 2078960 A1 EP 0571700 A1 JP 6296702 A KR 9607519 B1 MX 9300566 A1	28-10-1993 16-11-1993 22-10-1993 01-12-1993 25-10-1994 05-06-1996 01-10-1993
WO 9817215	A	30-04-1998	AU 720210 B2 AU 4996497 A CA 2241188 A1 EP 0934041 A1 JP 2001502581 T NZ 330838 A WO 9817215 A1 US 6238691 B1	25-05-2000 15-05-1998 30-04-1998 11-08-1999 27-02-2001 28-02-2000 30-04-1998 29-05-2001
EP 0344913	A	06-12-1989	AU 651900 B2 AU 1966592 A AU 630092 B2 AU 3397989 A CA 1333552 C DE 68928335 D1 DE 68928335 T2 EP 0344913 A1 ES 2106722 T3 JP 2026559 A US 5197945 A	04-08-1994 17-09-1992 22-10-1992 07-12-1989 20-12-1994 30-10-1997 19-03-1998 06-12-1989 16-11-1997 29-01-1990 30-03-1993
WO 0160296	A	23-08-2001	US 6566575 B1 AU 6626700 A BR 0017115 A CA 2398065 A1 CN 1434692 T EP 1263366 A1 JP 2003522596 T WO 0160296 A1	20-05-2003 27-08-2001 14-01-2003 23-08-2001 06-08-2003 11-12-2002 29-07-2003 23-08-2001